

## Exhibit A - Excerpt of Pramudji Deposition (4-11-2014)

1                   IN THE UNITED STATES DISTRICT COURT  
2                   FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
3                   CHARLESTON DIVISION

4           IN RE: ETHICON, INC.,  
5           PELVIC REPAIR SYSTEMS  
6           PRODUCTS LIABILITY LITIGATION           MDL NO. 2327

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7           Jo Huskey and Allen

8           Huskey,

9                   Plaintiffs,

10          v.

Case No. 2:12-cv-05201

11          Ethicon, Inc., et al.,

12                   Defendants.

13  
14                   ORAL DEPOSITION OF  
15                   CHRISTINA PRAMUDJI, M.D.  
16                   Friday, April 11, 2014

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18  
19  
20  
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24

1 the removal surgeries can be significantly  
2 more complicated than the original  
3 implantation surgery for the TVT-O, right?

4 MR. SNELL: Form.

5 A. It can be harder to find the  
6 sling if it's not a dyed sling.

7 BY MS. KIRKPATRICK:

8 Q. And the removal surgery requires  
9 dissection of some of the pelvic tissue,  
10 correct?

11 A. Well, it requires dissecting  
12 around the urethra, primarily.

13 Q. And that can cause additional  
14 scar tissue, correct, simply because you're  
15 having more surgery in the same location?

16 A. It could, yes.

17 Q. Are there any other complications  
18 that you think are risks that come from the  
19 removal surgery itself?

20 A. No.

21 Q. So just the possibility of  
22 additional scarring?

23 A. Yes.

24 Q. Okay. We've been talking a lot

1       about kind of the procedure that's used here.

2       You're not a biomaterials expert, correct?

3           A.       Well, I know about the materials  
4       that I use for surgery, so I would say that  
5       I -- you know, I'm knowledgeable about what I  
6       implant in patients.

7           Q.       Okay. What's the Ethicon TVT-O  
8       sling made of?

9           A.       Polypropylene.

10          Q.       Okay. What's added to that  
11       polypropylene?

12          A.       What's added to it?

13          Q.       Uh-huh.

14          A.       I don't know if anything's added  
15       to it.

16          Q.       Do you know if there's any  
17       antioxidants used in it?

18          A.       No, I don't know.

19          Q.       Do you know what its molecular  
20       weight is?

21          A.       I've seen it before, but I don't  
22       know off the top of my head.

23          Q.       Do you know whether it's been  
24       oxidized before it's been placed into a

1 woman's body?

2 A. No.

3 Q. Do you know anything about the  
4 process of oxidation of polypropylene?

5 A. No.

6 Q. And that's not the type of  
7 information -- you know that it's made of  
8 polypropylene, but you're not intending to  
9 offer opinions here concerning the chemical  
10 processes that are involved with  
11 polypropylene, correct?

12 A. I don't know about the chemical  
13 processes.

14 Q. Okay. So you would defer -- you  
15 would defer to other experts who would be  
16 biomaterials experts or who would be  
17 specialists in polypropylene for that  
18 particular type of information?

19 MR. SNELL: Form.

20 A. I know how it -- I focus on it  
21 from the perspective of my patients.

22 BY MS. KIRKPATRICK:

23 Q. Okay. So you focus, though, on  
24 how you believe the polypropylene sling

1 performs in your patients, both from an  
2 efficacy standpoint, correct, and from  
3 complications that you see?

4 A. From my experience and from the  
5 vast body of literature that's available on  
6 polypropylene slings.

7 Q. Okay. But I guess I'm just  
8 trying to figure out what the parameters of  
9 your testimony are. You're not going to come  
10 in and you're not planning on holding  
11 yourself out as an expert on polymers and  
12 polypropylene and degradation or any of those  
13 particular issues related to polypropylene,  
14 are you?

15 MR. SNELL: Form. And I will say  
16 she is. I am putting her up on that, and  
17 it is in her report.

18 BY MS. KIRKPATRICK:

19 Q. Okay. How does polypropylene  
20 degrade?

21 A. It doesn't degrade.

22 Q. So your opinion, sitting here  
23 today, that there is no way that any  
24 polypropylene that exists in this world can

1 degrade?

2 MR. SNELL: That's overbroad,  
3 form.

4 Go ahead.

5 A. That's a very broad question.  
6 You know, from how it's used in the body in  
7 sutures and in slings, it doesn't degrade;  
8 that's why it's a permanent suture. That's  
9 why heart surgeons rely on it and cardiac  
10 surgeons rely on it to sew up your aorta when  
11 you have aortic surgery.

12 So if it degraded, it would not  
13 be used in that application. There's no  
14 clinical degradation that occurs.

15 BY MS. KIRKPATRICK:

16 Q. So you believe that there's no  
17 evidence that exists, either in Ethicon's own  
18 documents or in the literature, that supports  
19 the theory that polypropylene sutures can  
20 degrade --

21 MR. SNELL: Form.

22 Go ahead.

23 BY MS. KIRKPATRICK:

24 Q. -- in vivo?

1 MR. SNELL: Form.

2 A. I mean, I can't say that there's  
3 nothing out there that they didn't do any  
4 kind of manipulation to polypropylene or look  
5 at it a certain way and found some  
6 degradation there, but does it matter to  
7 patients and to this case, no.

8 BY MS. KIRKPATRICK:

9 Q. Has Mr. Snell or any of the  
10 attorneys for Ethicon provided you with any  
11 Ethicon documents reflecting degradation of  
12 polypropylene sutures?

13 A. I mean, I think I saw some  
14 internal communication, I can't remember if  
15 it was from Mr. Kountze or from Mr. Snell, I  
16 don't remember, but I know that that is out  
17 there, that that was something that the  
18 engineers were talking about and Ethicon was  
19 talking about.

20 But clinically, I'm telling you  
21 it does not make a difference, and I don't  
22 believe that there's degradation that occurs  
23 that it makes any hill of beans' difference  
24 for patients.



1 Q. Okay. So let me just figure out  
2 what you are testifying about and what you're  
3 not testifying about. You don't have a basis  
4 for saying whether polypropylene does or  
5 doesn't degrade.

6 What you are here to offer your  
7 opinion on is that regardless of whether  
8 polypropylene degrades or doesn't degrade,  
9 there's no clinical significance to a  
10 particular patient?

11 A. I don't think it degrades.

12 MR. SNELL: Hold on, hold on,  
13 hold on. Form. That misstates, too.

14 Go ahead.

15 A. I don't think it degrades and I  
16 think there's other evidence that shows that  
17 it doesn't degrade.

18 BY MS. KIRKPATRICK:

19 Q. Have you asked Ethicon, in  
20 reaching that opinion, to provide you with  
21 all of the information that they have  
22 concerning the potential degradation of  
23 polypropylene sutures?

24 A. No.

1           Q.       And don't you think that the  
2       information that Ethicon has and the  
3       knowledge that Ethicon has concerning the  
4       degradation of polypropylene sutures would be  
5       something that you would want to see in  
6       reaching your opinions concerning the  
7       degradation of polypropylene sutures?

8                   MR. SNELL:   Form.

9           A.       No.

10       BY MS. KIRKPATRICK:

11           Q.       You don't think it's important  
12       what your -- what Ethicon has said about its  
13       own sutures for you to reach your conclusion.  
14       Is that right?

15           A.       Right.

16           Q.       Okay.   Have you ever tested it to  
17       see whether it degrades?

18           A.       No.

19           Q.       Have you ever looked at  
20       polypropylene under a microscope?

21           A.       I've seen pictures of it under a  
22       microscope.

23           Q.       Have you looked at it yourself?

24           A.       No.

1 Q. Have you ever looked at explanted  
2 polypropylene sutures and analyzed them to  
3 see whether there's any degradation in them?

4 A. No, I have not.

5 Q. Have you ever looked at explanted  
6 polypropylene mesh to see if there's any  
7 degradation in that mesh?

8 A. I've looked at -- when I've taken  
9 it out of patients, I've looked at it and  
10 it's intact.

11 Q. Okay. Let me just clarify. Have  
12 you ever looked at it microscopically to see  
13 whether it has degraded microscopically?

14 A. I've looked at the images that  
15 the pathologists have provided to me because  
16 I get images back from them.

17 Q. Okay. How many of those images  
18 have you looked at?

19 A. I don't know, 10, 20.

20 Q. Have you ever asked a pathologist  
21 to see whether the polypropylene had  
22 deteriorated?

23 A. No.

24 Q. That's not something that you

1       standardly do when you remove polypropylene  
2       from a woman?

3           A.       No, because it doesn't  
4       deteriorate.

5           Q.       How do you know that?

6                   MR. SNELL:   Form, asked and  
7       answered.

8           A.       Because it doesn't.   It's a  
9       permanent suture.   You can go back in 20  
10      years and you'll still find it in there.

11      BY MS. KIRKPATRICK:

12           Q.       And so your -- is it your opinion  
13      here that because 20 years from now, you can  
14      find a polypropylene suture where you  
15      implanted it and it has not completely  
16      disappeared, therefore it cannot degrade?

17                   MR. SNELL:   Form.

18           A.       20, 30, 40 years, it's going to  
19      be there.   It's not degrading.

20      BY MS. KIRKPATRICK:

21           Q.       Do you think it can crack?

22           A.       No.

23           Q.       Do you think that it can release  
24      particles from the surface?

1 A. No.

2 Q. Do you think that it changes its  
3 chemical composition in any way at all?

4 A. No.

5 Q. Do you think that polypropylene  
6 used in the body can change its molecular  
7 weight?

8 A. No.

9 Q. Do you think that polypropylene  
10 that is used in the body can undergo any  
11 mechanical changes to it?

12 MR. SNELL: Form.

13 A. Depending on where it's placed  
14 and what happens with that patient, it could  
15 move slightly, because it's -- you know, just  
16 the position of it, like a hernia repair, if  
17 a patient gained a lot of weight, it could  
18 change its position slightly, if that's what  
19 you're referring to. But it doesn't just  
20 change on its own.

21 BY MS. KIRKPATRICK:

22 Q. Okay. And once again, the basis  
23 for your opinion on that is when you have  
24 looked at the polypropylene that you've

1 removed, you don't visibly see deterioration?

2 MR. SNELL: Form.

3 A. That's part of it, but also  
4 because polypropylene is relied upon by  
5 surgeons throughout the world for the last 40  
6 years as a permanent suture. If we were  
7 having aortas busting open after 30 years, we  
8 wouldn't be relying on it.

9 BY MS. KIRKPATRICK:

10 Q. So that's the basis for your  
11 opinion here, it's not any independent study  
12 that you've done, correct?

13 MR. SNELL: Form.

14 A. In looking at the literature as  
15 well. It's not reported as degrading.

16 BY MS. KIRKPATRICK:

17 Q. You've never seen any literature  
18 that reports polypropylene degrading?

19 A. Not any significant good  
20 literature. Some remote studies.

21 Q. Okay. What literature have you  
22 been provided with by Ethicon regarding  
23 degradation? What articles have you looked  
24 at?

1           A.       I can't recall right now.

2           Q.       Okay. And when you say not any  
3           good literature, what literature are you  
4           referring to that would be -- I don't want to  
5           say bad literature just because it's the  
6           opposite of good -- that documents or deals  
7           with degradation of polypropylene in the  
8           body?

9           A.       I mean, I think there was maybe a  
10          polymer article or something like that that  
11          was talking about it in some journal, but I  
12          can't recall. But nothing in the major body  
13          of literature that has brought that up as an  
14          issue. It's just not an issue.

15          Q.       You don't believe that that's an  
16          issue at all?

17          A.       No.

18          Q.       And you don't believe that that's  
19          an issue that's been addressed in the medical  
20          and scientific literature?

21          A.       No.

22          Q.       And it's not an issue that was  
23          addressed in the materials that were provided  
24          to you by Ethicon, either from their internal

1 documents or from the literature that they  
2 provided you with, correct?

3 MR. SNELL: Form.

4 A. Correct.

5 BY MS. KIRKPATRICK:

6 Q. Okay. And you haven't done  
7 any -- you don't have any specialized  
8 training in polymer chemistry, do you?

9 MR. SNELL: Form.

10 A. Well, I'm a chemical engineer, so  
11 I had some training in polymers and  
12 chemistry.

13 BY MS. KIRKPATRICK

14 Q. Okay.

15 A. But, you know -- and that was a  
16 long time ago. But, I mean, my main concern  
17 is with patients, you know, the materials  
18 that I put in patients and how they -- what  
19 the literature bears out and how they respond  
20 to it.

21 BY MS. KIRKPATRICK:

22 Q. So when you take a TVT-O or any  
23 kind of midurethral sling out of a patient,  
24 does it look exactly the same as it did when